

## R E M A R K S

The Examiner has objected to claims 1-27 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter for which applicant regards as the invention. More specifically, the Examiner suggests that the limitation in independent claims directed to the first and second indicia's being independent of size is vague and indefinite. Applicant has amended independent claims 1 and 10 to overcome the Examiner's rejection. As such, applicant respectfully requests reconsideration in view of the following comments or, if the rejection is maintained, some type of clarification from the Examiner to explain why the Examiner feels such limitation is indefinite.

Initially, it is noted that only claims 1-7 and 9-17 contain the limitation directed to the first and second indicias being independent of size. As such, Applicant will direct his comments to these specific claims. Referring to claim 1, a microfluidic device is defined for displaying indicia in response to change of a predetermined parameter of a fluid flowing therethrough. The microfluidic device includes a body defining a channel for accommodating a flow fluid therethrough. A monitor structure is retained in the channel of the body at a user selected position within the flow of fluid. The monitor structure displays a first indicia in response to a predetermined parameter of the fluid having a first value and the second indicia in response to the predetermined parameter of the fluid having a second value. Claim 1 requires the first and second indicias to be independent of the size of the monitor. In other words, there is no relationship between the first and second indicias and the size of the monitor structure. By way of example, referring to the specification, the first and second indicias may correspond to a color change of the monitor structure. It is noted that a change in color of the monitor structure does not depend on the size of the monitor. Hence, the indicias are independent from the size of monitor structure and within the scope of the present invention. Of course, other changes in the indicias are possible which are not dependent on the size of the monitor structure. Given that the indicias displayed by the monitor structure do not depend on the size of the monitor structure,

unlike the structure disclosed in the Beebe et al. '872 patent as hereinafter described, it is believed that the limitation provided in independent claim 1 particularly points out and distinctly claims the subject matter of the present invention.

Applicant has amended independent claim 10 in a similar fashion as independent claim 1. As such, it is believed that claim 10 particularly points out and distinctly claims the subject matter of the present invention. Consequently, it is believed that claims 1-7 and 9-17 are in a proper form for allowance and withdrawal of the Examiner's objection to such claims is respectfully requested.

The Examiner has also rejected claims 1-27 under 35 U.S.C. § 102(e) as being clearly anticipated by Beebe et al., U.S. Patent No. 6,488,872. It is noted, however, that the Office Action makes no reference to claims 28-36 which are pending in the present application. As hereinafter described, applicant believes that the Examiner has failed to appreciate certain limitations provided in claims 1-27. Consequently, reconsideration of the Examiner's rejection is respectfully requested.

As heretofore described, claim 1 defines a microfluidic device for displaying indicia in response to a change in a predetermined parameter of a fluid flowing therethrough. The microfluidic device includes a body defining a channel accommodating a fluid flow therethrough. The monitor structure is retained in the channel of the body of the user-selected position within the fluid flow. The monitor structure displays a first indicia in response to a predetermined parameter of the fluid having the first body and a second indicia in response to a predetermined parameter having a second body. The first and second indicias are independent of the size of the monitor structure. In other words, there is no relationship between the first and second indicias and the size of the monitor structure. Consequently, it is believed claim 1 defines over the cited references.

The Beebe et al. '872 patent is directed to a method of fabricating a microfluidic device. The method includes the steps of providing a cartridge defining a chamber for receiving polymerizable material therein. A photomask is positioned on the top surface of the cartridge and the cartridge is exposed to ultraviolet light. The photomask corresponds to the geometry of a channel network to be formed within the microfluidic device. When polymerization is complete, the residual polymerizable material is drained from the cartridge in order to provide the channel network therein. Thereafter, the structural components may be formed in the channel utilizing the same process. As pointed out by the Examiner, one of such components includes a device that contains a responsive hydrogel.

Referring to Figs. 1a–1b of the '872 patent, a detection device for detecting a component in the biological fluid or other liquid media is provided. The device 100 contains a responsive hydrogel 102 in microchannel 104. Responsive hydrogel 102 contracts upon exposure to an analyte of interest, thereby allowing component A in a microchannel 108 to flow to a chamber 106 and mix with a component B in order to produce a detectable change, for example, a color change in chamber 106. The color change provides a macroscale response to a microscale event, i.e., contact of the analyte of interest with responsive hydrogel 102.

It can be appreciated from the above description that the structure described in the '872 patent is vastly different than the structure defined in independent claim 1. More specifically, the hydrogel sensor disclosed in the Beebe et al. '872 patent retracts in response to a stimulus so as to allow a dye to flow therepast. Consequently, the monitor structure disclosed in the '872 patent does not display a first and second indicia as provided by independent claim 1 since the monitor structure does not incorporate an implanted dye. Further, the color change provided in chamber 106 of the device 100 is directly dependent upon a change in the size of the responsive hydrogel 102. Again, this directly contradicts independent claim 1 which requires the monitor structure to display the first and second indicia and for the first indicia and the second indicia to be independent of the size of the monitor structure. Since the Beebe et al. '872 patent does not

disclose each and every limitation of independent claim 1, it is believed that claim 1 is not anticipated by the '872 patent. Consequently, it is believed that independent claim 1 is in proper form for allowance and such action is earnestly solicited.

Claims 2-9 depend either directly or indirectly from independent claim 1 and further define a microfluidic device not shown or suggested in the art. It is believed that claims 2-9 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Claim 10 defines a method for monitoring the environment within a microfluidic device. The method includes the steps of immobilizing a monitor structure in a channel of a microfluidic device and passing the fluid over the monitor structure. The monitor structure generates a visual display independent of the size of the monitor structure in response to a parameter of fluid having a predetermined value.

As heretofore described with respect to independent claim 1, nothing in the Beebe et al. '872 patent shows or suggests providing a monitoring structure that generates a visual display that is independent of the size of the monitor structure in response to exposure of the monitor structure to a parameter of the fluid having a predetermined value. Again, as heretofore described, in the Beebe et al., '872 patent, the optical properties of the device incorporating the hydrogel sensor are entirely dependent upon the size of the sensor. Consequently, it is believed that independent claim 10 defines over the cited reference and is in proper form for allowance.

Claims 11-17 and 28 depend from independent claim 10 and further define a method for monitoring the environment within a microfluidic device not shown and suggested in the prior art. It is believed that claims 11-17 and 28 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

It is also noted that claims 11-17 and 28 include the additional step of immobilizing a dye in the polymer matrix of the monitor structure. The Examiner suggests that page 8, line 18 + of the Beebe et al., '872 patent teaches a pH sensitive polymer mixture hydrogel. As such, in the Examiner's opinion, such a pH sensitive hydrogel reads on the claimed subject matter. However, there is nothing in the '872 patent that shows or suggests immobilizing a dye within a hydrogel, or shows or suggests a pH sensitive hydrogel that changes colors in response to a change in pH. The suggestion of such a structure is entirely absent from the cited references. More specifically, the '872 merely disclosed a device wherein a hydrogel sensor actuator changes size in response to a change in pH. Referring to Column 12, lines 62-65 of the '872 patent, it specifically discusses the ability of the pH sensor to contract and expand in response to changes in the pH. Hence, it is believed that claims 11-17 and 28 clearly define over the cited reference.

Referring to claim 18, a method is provided for monitoring the environment within the microfluidic device. The method includes the steps of mixing a dye in a prepolymer mixture in providing the same as a pregel. Thereafter, the pregel is injected in the channel with a microfluidic device and polymerized in the channel to form a monitor structure. The fluid is passed over the monitor structure in the channel such that the dye changes color in response to a parameter of the fluid having a predetermined value.

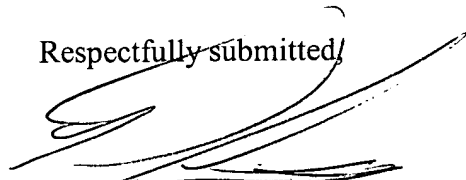
As heretofore described with respect to claims 11-17 and 28, nothing in the Beebe et al. '872 patent shows or suggests the steps of mixing the dye into a prepolymer mixture and injecting the prepolymer mixture to a channel of a microfluidic device to be polymerized. Such a methodology is entirely absent from the Beebe et al. '872 patent which merely provides a hydrogel that expands and contracts in response to exposure to a fluid having a predetermined parameter such as the value of pH. Consequently, it is believed that independent claim 18 defines over the cited reference and is in proper form for allowance.

Claims 19-27 depend either directly or indirectly from independent claim 18 and further define a method not shown or suggested in the prior art. It is believed that claims 19-27 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Finally, it is once again noted that the Examiner has provided no basis for rejecting claims 28-36. Such claims have not been withdrawn by applicant and are still pending in the present application. Applicant specifically notes that the Examiner has vacated his rejection of claims 29-36 under McDevitt et al., U.S. Patent No. 6,589,779. As such, clarification of the status of claims 28-36 is respectfully requested.

Applicant believes that the present application with claims 1-7 and 9-36 is in proper form for allowance and such action is earnestly solicited. Applicant believes that no additional fees are required in connection with the present submission. However, the Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,



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